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FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP
DATE : April 16, 2008
SUBJECT : U.S. Patent Appln. Serial No. 10/735,854
for *Osteosynthetic Implant With An Embedded Hinge Joint*
Our Ref.: 10139/13801

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Attorney Docket No. 10139/13801(00842-05PUS2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Frigg
Serial No. : 10/735,854
Filed : December 16, 2003
For : Osteosynthetic Implant With An Embedded Hinge Joint
Group Art Unit : 3733
Confirmation No. : 3166
Examiner : Richard R. Shaffer

Mail Stop: Appeal Brief - Patents
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By: *Oleg F. Kaplun* Reg. No. 45,559

Date: April 16, 2008

TRANSMITTAL

In response to the Notification of Non-Compliant Appeal Brief mailed on March 26, 2008, transmitted herewith please find a revised Appeal Brief for filing in the above-identified application. No fees are believed to be required. However, the Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: April 16, 2008

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RECEIVED
CENTRAL FAX CENTERAPR 16 2008 PATENT
Attorney Docket No.: 10139-13801IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
FRIGG)
Serial No.: 10/735,854) Group Art Unit: 3733
Filed: December 16, 2003) Examiner: R. Schaffer
For: OSTEOSYNTHETIC IMPLANT)
WITH AN EMBEDDED HINGE JOINT)
Confirmation No. 3166)

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Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on February 19, 2008, and pursuant to 37 C.F.R. § 41.37, Appellant presents this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's rejection of claims 2-7, 13-16, and 20 in the final Office Action dated October 17, 2007. The appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to Synthes (U.S.A.), the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claim 1 has been cancelled. Claims 8-12, 17-19, and 21-36 have been withdrawn from consideration. Claims 2-7, 13-16, and 20 have been rejected in the final Office Action of October 17, 2007. The rejection of claims 2-7, 13-16, and 20 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellant have been entered.

5. Summary of Claimed Subject Matter

This summary associates the claimed invention with certain subject matter of the specification. Nevertheless, since this association is only exemplary, the scope of the claimed invention is not limited to the description contained herein. Moreover, as an exemplary summary, this description does not purport to exhaustively list every place in the specification that supports the claimed features.

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In one aspect of the present invention, as exemplified in claim 2, an implant comprises at least one coupler (10) having at least two connecting elements (5) for engaging a first member (3) to a second member (1). (Specification at page 7, lines 3-16; Figures 1A and 1B). The connecting elements (5) permit the first member (3) to rotate with respect to the second member (1). (Specification at page 7, lines 23-29; Figures 1A and 1B). The connecting elements are pins that are pivot-mounted in the first member. (Specification at page 8, lines 11-14; Figure 2).

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claim 7 violates the written description requirement under 35 U.S.C. § 112, ¶1,

II. Whether claims 2-7, 13-16, and 20 are anticipated under 35 U.S.C. § 102(a) by United States Patent No. 4,029,091 to von Bezold et al. ("von Bezold").

7. Argument

With respect to the rejection of claim 7 based on the written description requirement, claim 7 recites that "the connecting elements are sized and configured for elastic deformation." Appellant assumed that the fault, as understood by the Examiner, derived solely from its dependency on claim 2, and that the amendment to claim 2 would overcome the rejection of all the listed claims, including claim 7. The Examiner is of a different mind, since in the Advisory Action he advises that the rejection of claim 7 remains in place. So an independent basis exists for rejecting claim 7 under the written description requirement, but Appellant does not understand the basis provided by the Examiner. As stated by the Examiner, the basis is that "[c]laim 7, which ultimately depends on claim 2, is directed towards the previously claimed

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embodiment of an integral flexible spring member extending between the ring and plate. Given applicant's arguments such is not what is being claimed anymore in claim 2, and therefore is directed to a non-disclosed embodiment." Appellant does not understand this argument and respectfully requests the Examiner to elaborate in the Examiner's Answer. Appellant argued that the cantilever elements 18a and 18b of von Bezold permit longitudinal, but not rotational, movement of lug 14. How this argument justifies the maintenance of the rejection of claim 7 is not seen.

With respect to the rejection based on Bezold, claim 2 recites an implant comprising a "coupler having at least two connecting elements for engaging a first member to a second member," the connecting elements permitting the first member to rotate with respect to the second member and "wherein the connecting elements are pins that are pivot-mounted in the first member."

In contrast, von Bezold shows a plurality of lugs providing spring-like extensions with each lug supported by a cantilever element 18 which acts as a resilient cantilever. That is, the cantilever elements 18 have a predetermine degree of stiffness and resilience to enable them to act as resilient cantilevers. That is, the stiffness and resilience of the cantilever elements 18 is selected to allow the elements 18 to act as spring flexing in the plane of the body 10 plate upon application of a magnetic field. This allows the lugs 14 to be moved laterally increasing the size of a gap on one side of a lug 14 while decreasing the gap on the other side to alter the longitudinal distance between the lugs 14. (Specification, col. 1, lines 55 - 62 and col. 2, lines 29 - 34). Thus, the cantilever elements 18 are moved laterally in the plane of the plate and alter only a longitudinal spacing of the lugs 14 without rotating the lugs 14 relative to the plate. Again with respect to the embodiment of Fig. 2, the lugs 14 are supported by cantilever elements 18a and 18b which "provide spring-like elastic suspension and some freedom of movement of the respective lug 14 *in the longitudinal direction.*" (Specification, col. 3, lines 11 - 14). That this longitudinal direction involves no rotation of the lugs 14 is made clear in the figures where

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arrows 20 represent the longitudinal direction. Thus, the lugs 14 move in a plane of the device along the arrow 20 and do not rotate with respect to the body 10 of the plate.

The cantilever elements 18 of von Bezold are rigidly coupled to the body 10 of the plate and allow the lugs 14 to move only by flexing. No other type of coupling is shown or suggested in von Bezold.

In the Advisory Action, the Examiner appears to argue that the claimed rotational movement is somehow inherent to the lug-cantilever combination since "one could have a screw located within the bore of the lug while causing a rotation of the lug (and screw) relative to the plate like applicant's device when not engaged with bone and arguably when engaged as well to a small degree." First, as to the supposed ability for this rotation to occur when the von Bezold implant is attached to bone, this is nothing more than groundless speculation that is belied by Figure 3, which shows that such rotation would not be possible since the bottom surface of lug 14 would be flush against film 17 and the underlying bone. As to the alleged capacity of lug 14 to rotate when the implant is not attached to a bone, the Examiner envisions a scenario in which a screw is located, presumably only partially, in lug 14 and pivoted manually to apply a torque against the circular inner surface of the lug opening, thereby causing lug to rotate in the manner claimed. Again, this too involves unsupported speculation, since the lug 14, rather than rotating in the manner contemplated by the Examiner, could just as well merely deform only in its portion closest to its through hole, while the portion closest to the outer circumference of lug 14 could remain rotationally undisplaced. In other words, a partial torsion that fails to involve a rotation of the lug as a whole could just as well be the result of the Examiner's scenario. Inherency, as the Examiner surely is aware, requires more than what might happen; it requires what must necessarily happen. Without having a precise knowledge of the dimensions of lug 14, particularly its thickness, or of how the material of lug 14 reacts to a torque applied thereto, one cannot argue, as the Examiner does here, that lug 14 necessarily rotates in the manner recited in the claims. In the absence of such knowledge, the partial torsion scenario proposed by Appellant is just as plausible.

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Thus, it is respectfully submitted that von Bezold neither shows nor suggests an implant comprising a "coupler having at least two connecting elements for engaging a first member to a second member," the connecting elements permitting the first member to rotate with respect to the second member and "wherein the connecting elements are pins that are pivot-mounted in the first member," as recited in claim 2 and that claim 2 is allowable. Because claims 3 - 7, 13 - 16 and 20 depend from and, therefore, include all of the limitations of claim 2, it is submitted that these claims are also allowable.

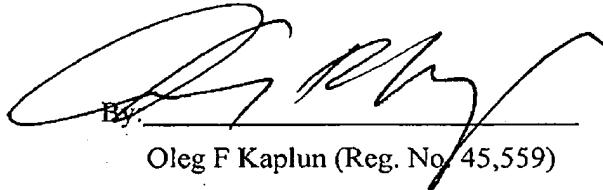
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8. Conclusions

For the reasons set forth above, Appellant respectfully requests that the Board reverse the final rejection of the claims by the Examiner.

Respectfully submitted,

Date: 4/16/08



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CLAIMS APPENDIX

1. (Cancelled)

2. (Previously Presented) An implant comprising: at least one coupler having at least two connecting elements for engaging a first member to a second member; wherein the connecting elements permit the first member to rotate with respect to the second member, and wherein the connecting elements are pins that are pivot-mounted in the first member.

3. (Original) The implant of claim 2, wherein the at least one coupler has an outer perimeter and the connecting elements extend from the outer perimeter.

4. (Original) The Implant of claim 2, wherein the at least one coupler has an outer perimeter and the connecting elements are spaced along the outer perimeter along a common axis defining an axes of rotation.

5. (Original) The implant of claim 2, wherein the first member has a through hole for receiving the coupler and the at least one coupler includes a borehole for receiving the second member.

6. (Original) The implant of claim 5, wherein the connecting elements are concentrically supported in the through hole formed in the first member.

7. (Original) The implant of claim 5, wherein the connecting elements are sized and configured for elastic deformation.

8. (Withdrawn) The implant of claim 2, wherein the at least one coupler comprises a first coupler and a second coupler wherein each coupler has at least two connecting elements and wherein the

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first coupler has an inner hole sized and configured to receive the connecting elements of the second coupler.

9. (Withdrawn) The implant of claim 8, wherein the first coupler is connected to the first member via the connecting elements and the second coupler includes a borehole for receiving the second member.

10. (Withdrawn) The implant of claim 9, wherein the first coupler permits rotation of the first member with respect to the second member about a first axis and the second coupler permits rotation of the first member with respect to the second member about a second axis.

11. (Withdrawn) The implant of claim 10, wherein the first axis and the second axis are offset with respect to each other.

12. (Withdrawn) The implant of claim 10, wherein the first axis and the second axis are perpendicular with respect to each other.

13. (Original) The implant of claim 2, wherein the connecting elements are tabs which are sized and configured to contact a through hole formed in the first member so that the first member can rotate with respect to the at least one coupler.

14. (Original) The implant of claim 2, wherein the first member is a bone plate having a screw hole extending from a top surface of the bone plate to a bottom surface of the bone plate, the screw hole being sized and configured to receive the at least one coupler via the connecting elements.

15. (Original) The implant of claim 14, wherein the second member is a bone screw and the at

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least one coupler further includes a borehole for receiving the bone screw so that the at least one coupler permits rotation of the bone screw with respect to the bone plate via the connecting elements.

16. (Original) The implant of claim 15, wherein the bone plate has a first thickness and the at least one coupler has a second thickness, the first thickness being greater than the second thickness.

17. (Withdrawn) The implant of claim 15, wherein the borehole formed in the at least one coupler has a tapered surface and the bone screw has a conical screw head sized and configured to contact the tapered surface so that the bone screw can rotate with respect to the at least one coupler.

18. (Withdrawn) The implant of claim 15, wherein the borehole formed in the at least one coupler includes an inner threading and the bone screw has an externally threaded bone screw head for threadingly engaging the inner threading.

19. (Withdrawn) The implant of claim 15, wherein the bone screw has an expandable head and means for fixedly securing the head to the borehole.

20. (Original) The implant of claim 15, wherein the at least one coupler is a circular element with an outer perimeter having the at least two connecting elements extending from the outer perimeter, wherein the connecting elements are sized and configured to contact the screw hole formed in the bone plate so that the bone screw can rotate with respect to the bone plate about an axis of rotation.

21. (Withdrawn) The implant of claim 15, wherein the at least one coupler comprises an inner

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coupler member and an outer coupler member, each member having at least two connecting elements.

22. (Withdrawn) The implant of claim 21, wherein the outer coupler member has an outer perimeter and an inner perimeter, the outer perimeter being sized and configured to contact the screw hole formed in the bone plate via the connecting elements and wherein the inner perimeter is sized and configured to engage the inner coupler member via the connecting elements, the inner coupler member incorporating the borehole for receiving the bone screw.

23. (Withdrawn) The implant of claim 22, wherein the connecting elements of the outer coupler member permits rotation of the bone screw with respect to the bone plate about a first axis and the connecting elements of the inner coupler member permits rotation of the bone screw with respect to the bone plate about a second axis, the first axis and the second axis being offset with respect to one another.

24. (Withdrawn) The implant of claim 15, wherein the implant further comprises a second bone plate, the second bone plate having at least one screw hole for receiving a second coupler, the second coupler having a borehole for receiving the bone screw so that the second coupler is alignable with respect to the at least one coupler connected to the first bone plate so that the bone screw can pass through the boreholes formed in the first and second couplers, respectively, at an oblique angle.

25. (Withdrawn) The implant of claim 2, wherein the first member is a body of a pedicle screw having a first end and a second end, the first end having a transverse channel for receiving a longitudinal spinal rod and the second end having a borehole sized and configured to receive the at least one coupler via the connecting elements.

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26. (Withdrawn) The implant of claim 25, wherein the second member is a bone screw and the at least one coupler includes a screw hole for receiving the bone screw so that the at least one coupler permits rotation of the bone screw with respect to the body.
27. (Withdrawn) The implant of claim 26, wherein the screw hole formed in the at least one coupler has a tapered surface and the bone screw has a conical screw head sized and configured to contact the tapered surface so that the bone screw can rotate with respect to the at least one coupler.
28. (Withdrawn) The implant of claim 26, wherein the screw hole formed in the at least one coupler includes an inner threading and the bone screw has an externally threaded bone screw head for threadingly engaging the inner threading.
29. (Withdrawn) The implant of claim 26, wherein the bone screw has an expandable head and means for fixedly securing the head to the borehole.
30. (Withdrawn) The implant of claim 2, wherein the first member is a vertebral endplate having a borehole for receiving the at least one coupler via the connecting elements.
31. (Withdrawn) The implant of claim 30, wherein the second member is a connecting member and the at least one coupler includes a hole for receiving the connecting member so that the at least one coupler permits rotation of the connecting member with respect to the vertebral endplate via the connecting elements.
32. (Withdrawn) The implant of claim 31, wherein the implant includes two vertebral endplates, each endplate having a borehole for receiving its respective coupler via the connecting elements, and wherein each coupler includes a hole for receiving an end of the connecting member so that

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the connecting member interconnects the vertebral endplates.

33. (Withdrawn) The implant of claim 2, wherein the first member is an intervertebral implant having a body with a top vertebra engaging surface, a bottom vertebra engaging surface, and a plurality of side surfaces extending therebetween, and wherein at least one of the top and bottom vertebra surfaces includes a borehole which is sized and configured to receive the at least one coupler so that the at least one coupler can rotate with respect to the implant via the connecting elements.

34. (Withdrawn) The implant of claim 33, wherein the top and bottom bone engaging surfaces each include a borehole for receiving a respective coupler via the connecting elements.

35. (Withdrawn) The implant of claim 33, wherein the top and bottom vertebra engaging surfaces are convex.

36. (Withdrawn) The implant of claim 33, wherein the body further comprises at least one through hole extending from one side surface to another side surface.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.